October 14, 2002

Technical Appendix for
The cost of operating institutional review boards (IRBs)

Todd H. Wagner, Ph.D.[1,2]
Aman Bhandari, MPH[1]
Gary L. Chadwick, Pharm D, MPH.[3]
Daniel K. Nelson, MS[4]

This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service (MRR 00-019). This work was presented at Human Subjects Research Subcommittee - Committee on Science, National Science and Technology Council, Washington, D.C., January 10, 2001. It was also presented as a poster at the ARENA national conference, December 2, 2001, Boston MA. The views expressed in this article are strictly those of the authors and do not necessarily reflect the Department of Veterans Affairs, Stanford University, the University of Rochester or the University of North Carolina.

Affiliations
[1] VA HSR&D Health Economics Resource Center, Menlo Park, CA.
[2] Department of Health Research and Policy, Stanford University School of Medicine, Stanford, CA.
[3] University of Rochester, Rochester, NY
[4] University of North Carolina-Chapel Hill, Chapel Hill, NC

This appendix describes in greater detail the methods for calculating the cost of operating IRBs. Two sources were used in developing these estimates. We relied heavily on the Bell Report,[1] written under contract to OPRR by James Bell and Associates. The Bell Report was especially helpful in identifying personnel characteristics and effort in the low- and high-volume IRBs. Second, we used expenditure data from the University of North Carolina at Chapel Hill to identify the costs of supplies, education and training. For face validity, we compared these estimates to an ongoing survey of 18 institutions.

The appendix has three sections. The first section describes the calculation of IRB costs. The second section describes the calculation of the "adequate" costs, in which IRB costs were calculated after limiting the staff workload to 350 actions per year. The third and final section is the sensitivity analysis.

1. Costs of operating IRBs

Calculating the costs of operating high-volume and low-volume IRBs involves an economic production function, where we combine quantity and price estimates for the inputs. The inputs include personnel, space, training and education, and supplies. The IRB produces a service, which is the review of protocols and adverse event reports, known generally as actions.

To calculate the personnel costs, we multiplied personnel time by personnel costs (salary plus benefits). We included a benefit rate of 28%. The number of full-time equivalent employees (FTE) is listed in Table 1. This information came from the Bell Report. The one exception was that a dedicated administrative assistant (i.e., clerical help) and a database analyst was added to the high-volume sites, solely to handle the volume of work, based on expert opinion.

Table 1: Total personnel time per institution: by IRB volume

Personnel	FTE	% of IRBs
High-volume institutions (4 IRBs)		
Director	1	100%
Administrative staff[1]	2	85%
Analyst / database manager	1	100%
Administrative assistant	1	100%
Chairs (4 chairs)[2]	0.5 each (2 FTE)	100%
Committee members'[2] (19.7 members)	0.05 FTE each	100%
Low-volume IRB		
Director[1]	0.5	100%
Administrative staff[1]	0.5	40%
Analyst / database manager	0	0%
Administrative assistant	0	0%
Chair's time total[3] (1 chair)	0.03	100%
Committee members'[3] (10.5 members)	0.009	100%

[1] Not all IRBs had staff members; this represents the percentage of IRBs that had staff members according to the Bell Report[1]

[2] High-volume sites had 4 chairs (0.5 FTE per chair), 19.7 members (5% FTE per member)

[3] Low-volume sites averaged 1 chair (3% FTE), 10.5 members (.9% FTE per member)

The Bell Report indicated that personnel experience differed in the low and high-volume IRBs (Bell Report pages 25-28). High-volume sites were generally staffed with more experienced chairs, members and directors. Translating this into costs suggest that the salaries at low-volume sites are less. Given this information and the belief that the high-volume IRBs are likely to be at more prominent research institutions, we discounted the salaries at the low-volume sites (see Table 2).

Salary estimates were obtained from a human resources company that tracks salaries across the United States, including those for biomedical personnel (www.salary.com). These salary estimates were then varied in the sensitivity analysis. With the staffing information listed in Table 1 and the salaries listed in Table 2, we estimated the personnel costs. It should be noted that with these salaries, the results may not generalize to non-biomedical IRBs or to independent, centralized IRBs.

Table 2: Base salary estimates

	Base	Benefit	Total
High-volume IRB			
Director	$ 75,000	28%	$ 96,000
Administrative staff[1]	$ 45,001	28%	$ 57,601
Analyst / database manager[1]	$ 48,334	28%	$ 61,868
Administrative assistant[1]	$ 33,155	28%	$ 42,438
Chair (per chair)	$ 115,000	28%	$ 147,200
Members (per member)	$ 75,000	28%	$ 96,000
Consultants			donated
Low-volume IRB			
Director	$ 55,000	28%	$ 70,400
Administrative staff[1]	$ 45,001	28%	$ 57,601
Analyst / database manager[1]	$ 48,334	28%	$ 61,868
Administrative assistant[1]	$ 33,155	28%	$ 42,438
Chair (per chair)	$ 75,000	28%	$ 96,000
Members (per member)	$ 55,000	28%	$ 70,400
Consultants			Donated

[1] Source: www.salary.com. The estimates reflect national average salaries based on jobs that most closely matched the job characteristics.

The IRB also uses office space that costs money (i.e., capital costs). Many institutions own this space, while others rent. For those that own, it would be necessary to calculate the financing costs of debt or bonds. This can be extremely difficult due to differences at each site. Based on past research,[2] we calculated space requirements and then estimated space costs based on annual rental rates per square foot. Rental rate estimates were obtained from two internet real estate web sites (www.reis.com and http://www.oncorintl.com/). Based on these services, we used $34.71 per square foot per year as the estimated rental rate. However, rental rates vary tremendously depending upon geographic location. For example, as of June 2000, the average rental rates in San Francisco exceeded $65 per square foot per year, while rates in Raleigh-

Durham were approximately $18 per square foot per year. Space costs are presented in Table 3, and these rates were varied in the sensitivity analysis.

Table 3: Space needs

Space (rental)	sq ft	Rental costs
High volume		
Director	100	$ 3,471
Admin staff effort engaged in IRB work	64	$ 2,221
Administrative assistant	64	$ 2,221
Computer database analyst	64	$ 2,221
Filing	300	$ 10,413
Meeting room[1]	180	$ 3,124
Hallway	120	$ 4,165
Copy room	100	$ 3,471
IRB chair[3]	100	$ 3,471
Low volume		
Space (rental)		
Director	100	$ 3,471
Admin staff effort engaged in IRB work	64	$ 2,221
Administrative assistant	64	$ 2,221
Computer database analyst	64	$ 2,221
Filing	100	$ 3,471
Meeting room[2]	180	$ 1,562
Hallway	40	$ 1,388
Copy room	25	$ 868
IRB chair	100	$ -

Note: Source: www.oncorintl.com and www.reis.com.
[1] Meeting room 50% shared with other department
[2] Meeting room 25% shared with other department
[3] Assumed that all chairs share one office

An IRB needs computers to work efficiently. We assumed that every person had a computer at his or her desk. The annual computer costs were based on a $2000 computer with a five-year life span and no salvage value. Using straight-line depreciation, this was approximately $400 per year for each computer. We also assumed that the high-volume sites had a local area computer network (LAN). With depreciation costs and annual maintenance and upkeep, the LAN was valued at $5000 per year.

For the other basic office supplies, including copy machines, telephones, fax machines and miscellaneous supplies, we used expenditure data from the University of North Carolina at Chapel Hill. The amount they spent on supplies, including paper, copying, phones, and faxes, totaled $8.10 per action in 1999. We then inflated this using the Consumer Price Index to 2001 ($8.33). To calculate the total supply costs, we multiplied $8.33 by the number of actions. The total supply costs are listed in Table 4 and then varied in the sensitivity analysis. This model assumes that supply costs vary perfectly with the number of actions. In fact, this assumption may be incorrect as high volume IRBs may have economies of scale because they are better able

to spread the costs of the copy machine and the fax machine. Because we had no data on this, we assumed that the rate of $8.33 was the same at the low- and high-volume IRBs. It should be noted, however, that if there are economies of scale with regard to supplies then the difference in the average cost per action reviewed between the low- and high-volume IRBs would be even greater.

Table 4: The cost of supplies

	Units	Unit cost	Total
High-volume IRB			
Supplies cost per action	2780	$ 8.33[1]	$ 23,157
Computer network (LAN)	1	$ 5,000	$ 5,000
Computers	7	$ 400	$ 2,800
Supplies subtotal			$ 30,957
Low-volume IRB			
Supplies cost per action	96	$ 8.33[1]	$ 799
Computer network (LAN)	0	$ 5,000	$ -
Computers	2	$ 400	$ 800
Supplies subtotal			$ 1,599

[1] From expenditure data from the University of North Carolina at Chapel Hill, inflated to 2001

The Bell Report discusses the educational sessions and training for the IRB chair and new orientation for members (Bell Report page 31-32). In addition to the personnel time, which is already covered, the cost of training and education sessions includes manuals and educational material. Other costs of education include journal and newsletter subscriptions as well as the costs of sending staff members and IRB chairs to national conferences and training meetings. From expert interviews, we estimated that education and training for each chair cost $1000. In addition, education and training for staff members was estimated at $1000 per FTE per year, excluding the committee members. This estimate was varied in the sensitivity analysis.

The estimated total cost of operating a high- and low-volume IRB is listed in Table 5. This is the sum of the personnel costs, space costs, supplies and training and education.

Table 5: Estimated actual cost of operating an IRB

	High-volume IRB	Low-volume IRB
Personnel costs	$693,716	$60,045
Space costs	$37,001	$12,982
Supplies	$30,957	$1,599
Education and training	$9,000	$2,000
Total	$770,674	$76,626

2. Adequate costs of operating IRBs

To calculate the adequate costs of operating an IRB, the first step was to determine the adequate staffing needed to review the actions received by low- and high-volume IRBs. This is complicated because not all actions take equal amounts of time to review in committee. In addition, expedited and exempt protocols do not have to be reviewed in a full committee meeting. The Bell Report indicated the time it takes to review each type of action, and this is presented in Table 6.

Table 6: Distribution of IRB time in an average meeting

	Low-volume IRB	High-volume IRB
Initial review	66%	66%
Continuing	13%	13%
Amended	7%	7%
Adverse event reports / other issues	14%	14%
Total	*100%*	*100%*

Source: Bell Report[1]

IRBs respond to changes in workload by altering: 1) the length of each committee meeting, 2) the number of meetings per month, and 3) the number of committees. According to the Bell Report, low-volume IRBs had approximately 7 meetings per year with a per meeting mean duration of 105 minutes. Large-volume IRBs had 12 meeting per year and each meeting lasted approximately 145 minutes. Based on this, we assumed that to complete all of the reviews in a timely manner, the institution varied the number of IRBs.

We know from the Bell Report that low- volume IRBs spend an average of 105 minutes per meeting. Ten minutes of this is taken up with policy discussion. With the remaining 95 minutes, 66% (63 minutes) of that is spent in initial reviews. Similarly, 12, 7, and 13 minutes are spent in continuing reviews, amendments, and adverse event reports. These amounts are listed in Table 7 for both the low- and high-volume IRBs.

Table 7: Time spent reviewing actions in one committee meeting

	Low-volume IRB	High-volume IRB
	(minutes)	
Policy issues	10	10
Initial	63	89
Continuing	12	18
Amended	7	9
Adverse event reports / other issues	13	19
Total	*105*	*145*

Source: estimated from Bell Report

The Bell Report also has information on the average time is takes a committee to review each type of action. Table 8 lists the review times per unit. Importantly, the Bell Report found that higher volume institutions took about one seventh the time a lower volume institution took. This could indicate differences in quality, but it could also be explained by scale efficiencies. Through repetition, high volume IRBs may be able to refine their operation, essentially becoming more efficient with practice.

Table 8: IRB committee review time by type of review

	Low-volume IRB	High-volume IRB
	(minutes)	
Per initial review	21.3	3.0
Per continuing review	4	2
Per amended review	4	2
Per adverse event report	4	2

Source: estimated from Bell Report

With these data, we have the information necessary to estimate the number of reviews that are done in the average meeting. These totals are listed in Table 9.

Table 9: Number of actions reviewed in a meeting

	Low-volume IRB	High-volume IRB
Initial reviews	3	23
Continuing reviews	3	9
Amended reviews	2	5
Adverse event reports	3	9

Source: estimated from Bell Report

We can combine the information presented in Table 9 with data on the number of actions reviewed at low- and high-volume IRBs. From the Bell Report, we know that the average low-volume IRB reviews 96 actions per year, while the average high-volume IRB reviews 2,780 actions per year. The majority of these actions are initial and continuing reviews (see Table 10).

Table 10: Projected number of actions to be reviewed by IRBs

	Low-volume IRB	High-volume IRB
Initial		
full	19	468
expedited	8	206
exempted	5	119
Continuing	36	879
Amended	19	472
Adverse event reports	9	635
Total number of actions	*96*	*2,780*

Source: estimated from Bell Report
May not add due to rounding

Given the number of actions listed in Table 10, we calculated the number of committees it would take to process them. This was obtained by dividing the projected number of actions by the number of actions that can be reviewed in a meeting, if appropriate (see Table 9); this average was weighted by time per action. We know from the Bell Report that low-volume IRBs have approximately 7 meetings per year and high-volume IRBs have 12 meetings a year. With this information, we are able to estimate the number of committees needed to process all of the actions: 1 IRB for the low-volume institution and 4 IRBs for the high-volume institution.

The number of committees dictates the number of committee chairs and the number of committee members. For the low-volume and high-volume IRBs, we assumed a standard committee was comprised of a chair and nine committee members. For the high-volume IRBs, the IRB chair, assumed to be a physician, was allocated a 0.5 FTE and committee members were assigned 0.05 FTE. For the low-volume IRBs, the IRB chair, assumed to be a physician, was allocated a 0.25 FTE and committee members were assigned 0.02 FTE. The IRB director was assumed to have doctoral-level training. For high-volume IRBs, we added one FTE administrative assistant and one FTE database analyst. Benefits were calculated at 28% of the base salary. FTE salaries, benefits and total personnel costs are listed in Table 11. If the position was only a fraction of the FTE, then the personnel cost were allocated proportionately. Recall that the number of actions dictates the number of administrative staff (350 actions per FTE).

Table 11: Estimated personnel costs

	FTEs	Total
High-volume IRB		
Director	1	$ 96,000
Administrative Staff	5.5	$ 460,810
Database analyst	1	$ 61,868
Administrative assistant	1	$ 42,438
Chairs (4 chairs)	0.5 each	$ 294,400
Members (36 members)	0.05 each	$ 172,800
Consultants		not included
Subtotal		$ 1,128,316
Low-volume IRB		
Director	0.5	$ 35,200
Administrative Staff	0.5	$ 28,801
Analyst / database manager	0	$ -
Administrative assistant	0	$ -
Chair (1 Chair at 25% FTE)	0.25	$ 24,000
Members subtotal (9 members at 2% FTE each)	0.02 each	$ 12,672
Consultants		not included
Subtotal		$ 100,673

Source: www.salary.com
See Table 2 for salary details
The estimates reflect national average salaries based on jobs that most closely matched the job characteristics.

Based on the adequate staffing, we can calculate the space requirements as the additional professional staff members need office space. The estimated adequate space costs are listed in Table 12.

Table 12: Estimated space costs

Space costs	Low-volume	High-volume
Director	$ 3,471	$ 3,471
Staff	$ 2,221	$ 17,772
Administrative assistant	$ -	$ 2,221
Computer analyst	$ -	$ 2,221
filing	$ 3,471	$ 10,413
meeting room	$ 1,562	$ 3,124
hallway	$ 1,388	$ 4,165
copy room	$ 868	$ 3,471
IRB chair	$ -	$ 3,471
Subtotal	$ 12,982	$ 50,330

Note: Estimated the rental per square foot was $34.71 per year
Source: www.oncorintl.com and www.reis.com.
[1] 50% of a meeting room rented from other department
[2] Assumed that all chairs share one office
[3] 25% of meeting room rented from other department

There were no changes in the estimated supply costs. From expert interviews, we estimated that education and training for each chair cost $1000. In addition, education and training for staff members was estimated at $1000 per FTE per year, excluding the committee members. This estimate was varied in the sensitivity analysis. Table 13 shows the total adequate costs for operating low- and high-volume IRBs.

Table 13: Estimated total adequate cost of operating an IRB

	High-volume IRB	**Low- volume IRB**
Personnel costs	$ 1,128,316	$ 100,673
Space costs	$ 50,330	$ 12,982
Supplies	$ 34,157	$ 1,999
Education and training	$ 15,000	$ 2,000
Total	$ 1,227,802	$ 117,653

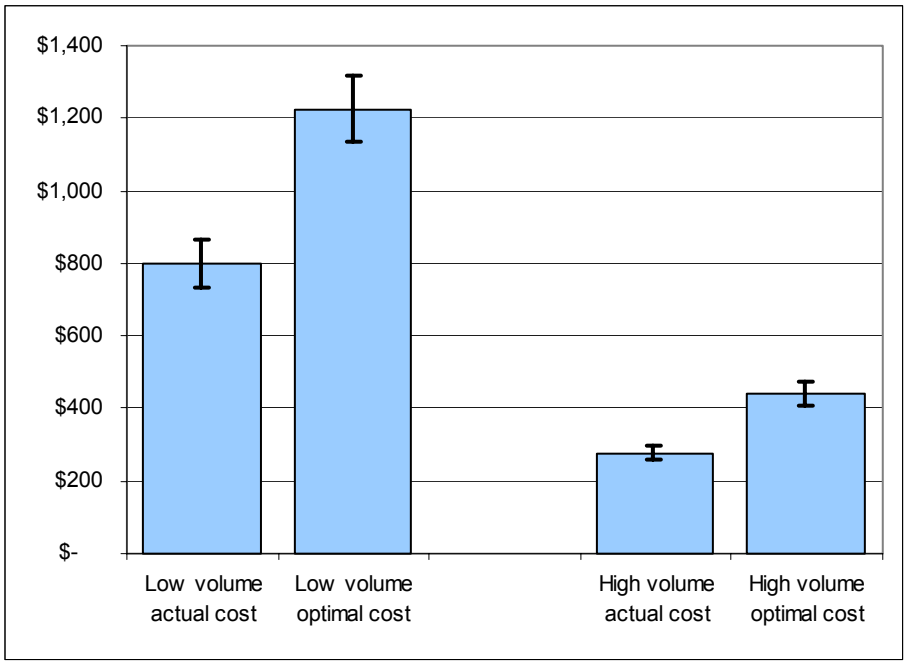
Note: may not add due to rounding

3. Sensitivity analysis

In the sensitivity analysis, we systematically varied the four inputs: personnel costs, space costs, supplies and training and education costs. For personnel costs, we varied the salary rates ± 20%. For the space costs (i.e., rental cost per square foot per month), the starting point was $20 and we varied this ±$15. We varied the supplies costs by adjusting the cost per action ±$5. Finally we adjusted the training and education costs by ±$500 and +$4000. Each input was varied while holding the other inputs constant.

The sensitivity analysis shows that the there is much more variability in the low-volume IRB sites. This finding in itself is interesting as it suggests that slight changes in funding or costs can have a large effect on the average cost per action reviewed. This variability can be seen in Figure 1, where the bars represent the baseline costs and the whiskers represent the extreme bounds from the sensitivity analysis. Otherwise the costs were most sensitive to rental rates and moderately sensitive to salary estimates.

Figure 1: Average cost per action



Note: bars represent the base case and the whiskers represent the extreme bounds from the sensitivity analysis.

Lastly, if high volume IRBs are able to use chairs and vice chairs, then this will lead to a greater savings for them and a larger discrepancy between the high and low-volume sites (i.e. greater economies of scale). If the high-volume IRB instituted two chairs (0.5 FTE) and two vice chairs (0.30 FTE) then the total savings would be approximately $59,280 (8%). These saving cannot be realized in the low-volume IRBs.

References

1. James Bell & Associates. Evaluation of NIH implementation of Section 491 of the Public Health Service Act, mandating a program of protection for research subjects. Arlington, VA: http://www.nih.gov/grants/oprr/hsp_report/hsp_final_rpt.pdf, 1998.

2. Rosenheck R, Frisman L, Neale M. Estimating the capital component of mental health care costs in the public sector. Administration and Policy in Mental Health 1994; 21:493-509.